

5. Proof of Freedom Procedures

5.1 Criteria for Proof of Freedom

The OIE Terrestrial Animal Health Code conditions for regaining free status following an FMD outbreak in a previously FMD-free country are given in Article 2.2.10.7 of the 14th edition of the Code 2005, which distinguishes between countries or zone where (routine) vaccination is practised and countries or zone where (routine) vaccination is not practised. One of the following waiting periods is applied:

1. When an FMD outbreak or FMDV infection occurs in an FMD-free country or zone where (routine) vaccination is not practised, one of the following waiting periods is required to regain the status of FMD-free country or zone where (routine) vaccination is not practised:

- 3 months after the last case where a stamping-out policy and serological surveillance are applied in accordance with Appendix 3.8.7; OR
- 3 months after the slaughter of all vaccinated animals where a stamping-out policy, emergency vaccination and serological surveillance are applied in accordance with Appendix 3.8.7; OR
- 6 months after the last case or the last vaccination (according to the event that occurs the latest), where a stamping-out policy, emergency vaccination not followed by slaughtering of all vaccinated animals, and serological surveillance are applied in accordance with Appendix 3.8.7, provided that a serological survey based on the detection of antibodies to non-structural proteins of FMDV demonstrates the absence of infection in the remaining vaccinated population.

2. When an FMD outbreak or FMDV infection occurs in an FMD free country or zone where vaccination is practiced, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is practiced:

- 6 months after the last case where a stamping-out policy, emergency vaccination and serological surveillance in accordance with Appendix 3.8.7 are applied, provided the serological surveillance based on the detection of antibodies to non-structural proteins of FMDV demonstrates the absence of virus circulation; OR
- 18 months after the last case where a stamping-out policy is not applied, but emergency vaccination and serological surveillance in accordance with Appendix 3.8.7 are applied, provided that the serological surveillance based on the detection of antibodies to non-structural proteins of FMDV demonstrates the absence of virus circulation.

5.2 Serological Surveillance

OIE targets for post-outbreak FMD surveillance in a previously FMD-free country are referenced in Appendix 3.8.7. While specifying stratification of the population in which to target surveillance, it recommends an increased level of sampling within zones considered to be at a higher likelihood of FMDV infection. It also specifies that the sampling strategy should give a 95% probability of detecting evidence of FMD or FMDV infection if it is present in 1% of the

primary sampling units. Risk assessment officers will assist in determining appropriate sampling levels specific to the outbreak area considering the estimated prevalence.

Thus, sero-surveillance is carried out in two distinct areas in relation to positive premises, within a 3-km radius (Infected Zone) and between 3 and 10 km from each positive premises (Surveillance Zone).

5.2.1 Within the Infected Zone

Surveillance in the Infected Zone will include clinical examinations by veterinarians of all remaining susceptible animal populations and serology on sheep and goats. The serological surveillance will be required for sheep and goats that have not been in direct and close contact with infected bovines for at least 21 days after the elimination of susceptible animals on the holding and the preliminary C&D. The sampling should be sufficient to ensure the detection of a 5% prevalence with a level of confidence of 95%. This survey will be supplemented by clinical assessment and serological results of sentinels from infected premises. If wildlife is present, it would also be necessary to demonstrate FMD freedom in these populations.

Where there has been a high concentration of outbreaks, the UK employed serological surveillance additional to that described above resulting in >95% of holdings with sheep/goats in the county being serologically examined. The UK employed a second tier of sampling that if sero-positive animals were found in any herd/flock, the whole group was re-sampled seven days later with each animal in the group individually identified. If only one sero-positive animal was found in a management group after rebleeding, only that animal was killed but if more than one was sero-positive on rebleeding, all the sheep/goats in the management group were killed. Before depopulation, any sero-positive sheep were probanged. If positive, the holding was confirmed as having disease and control measures were applied accordingly.

5.2.2 Within the Surveillance Zone

In the UK, sampling in this zone took place some considerable time after Infected Zone sampling had been completed. The EU required that at least 21 days elapse after preliminary cleaning and disinfection had been completed on any positive premises within 10 km.

Serological sampling will focus on premises where sheep and goats have not been in direct and close contact with bovine animals during a period of at least 21 days before taking the samples. Samples will be collected from as many herds/flocks as required to detect a disease prevalence of 1% at a level of confidence of 95%. Note that the EU specifies 95% confidence of locating at least one infected premises if the estimated prevalence of the disease was 2% equally distributed throughout the zone. The additional sampling to 1% prevalence is consistent with that in the Infected Zone. In any case, not more than 60 samples per herds/flocks and from all sheep and goats if there are less than 15 sheep and goats on the premises.

In the UK, the sero-surveillance program utilized the facilities of five laboratories with a potential peak testing capacity of 200,000 samples a week in November 2001. It is anticipated that additional regional laboratories will be used in Canada to supplement facilities at the NC-FAD in Winnipeg. In addition to sero-surveillance, susceptible livestock will be inspected as part of the epidemiological inquiries during the outbreak and as official veterinary inspection before movements being licensed throughout the outbreak. Intensified ante- and post-mortem inspection will be implemented in slaughter plants before lifting zone restrictions.

Once movement restrictions have been lifted, serological surveillance will continue at animal concentration points such as at sales yards, abattoirs and shows. Susceptible wildlife in the

Surveillance Zone would have to demonstrate freedom from FMD through hunting or selective capture surveys.

The protocol above is consistent with EU surveillance standards and the OIE Appendix 3.8.7, which defines an active surveillance program at 95% probability of detecting evidence of FMD or FMD V if it is present in 1% of the primary sampling units (herds/flocks). However, it exceeds the 95% probability of detecting a serological prevalence of 20% within management groups based on the presumption that if a herd is infected a significant time after the cessation of vaccination, it would be expected that the serological prevalence will exceed 20%.

5.3 Release of Control Area Restrictions

Measures in the Infected Zone shall be maintained until at least 21 days have elapsed since the elimination of all animals of susceptible species on premises considered to be FMD positive, completion of C&D, *and* a survey completed with negative results (clinical and serological for sheep and goats) in all premises with susceptible species. The EU recommends that restrictions of the Surveillance Zone be applied throughout the Control Area for an additional 15 days. This measure does not appear to be necessary provided that serological sampling within the Surveillance Zone has also yielded negative results. Thus for Canada, the Control Area will be lifted upon completion of serological sampling and the investigation of any serological reactors with negative results.

5.4 Disposition of Vaccinates

If vaccination was used in the outbreak, FMD vaccinates will still be subject to movement restrictions as infected place declarations were imposed during the process of vaccination. The final decision matrix *Are resources sufficient for FMD vaccinate slaughter?* will be considered by the Program Support Unit to the NERT. There are two routes by which a country that practices emergency vaccination can re-establish OIE country freedom without vaccination:

- three months after slaughter all vaccinates and/or last case of FMD (Article 2.2.10.7);
- six months after the last case or last vaccination (according to the event that occurs the latest) where a stamping-out policy, emergency vaccination not followed by the slaughtering of all vaccinated animals, and serological surveillance based on the detection of non structural protein (Article 2.2.10.7).

It is imperative that a cost-benefit analysis be conducted for trade lost during the additional three-month period if vaccinates are not slaughtered and a serological test is available and accepted by major trading partners *or* the additional nine months if vaccinates are not slaughtered and a serological test is not available or, if available, not acceptable to major trading partners.

In the Netherlands FMD outbreak in 2001, a study demonstrated that by destroying vaccinated livestock as soon as possible after vaccination, the industry would experience income losses of 0.5% and 1,340 person-years of employment annually, whereas if vaccinated stock were kept alive, extending export bans from a period of four months to at least a year, the sector would lose 2-3% of income and 7,000 person-years of employment. Thus, the immediate slaughter of vaccinates, which allowed the country to quickly regain FMD-free without vaccination status, delivered a significant economic advantage. It is thus unlikely that under the current export restrictions for FMD vaccination, that FMD vaccinates would be maintained in an economy dependent on trade.

Vaccinated animals ordered destroyed will be compensated in the same manner as FMD infected and contact animals ordered destroyed under the *Health of Animals Act*. Some of the compensation costs may be recovered if the products and by-products of vaccinated animals can be traced and marketed.

5.5 Country Freedom Declaration

Canada will make application to the OIE after meeting the requirements outlined above in Paragraph 5.1 in the case of emergency vaccination. The reinstatement of FMD-free status will require formal submission detailing the FMD policy, eradication procedures, surveillance and monitoring, veterinary infrastructure, industry organisation and, if vaccinates have been slaughtered, the tracking system for vaccinates and proof of slaughter. Acceptance of the claim for country freedom may also involve an inspection by an international panel of experts to review the eradication program and all available data to verify freedom.